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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,154	01/17/2002	Howard Milne Chandler	0141-2004	3461
7590 12/18/2003 Kevin m. Farrell, Pierce Atwood One New Hampshire Avenue Suite 350 Portsmouth, NH 03801			EXAMINER HANDY, DWAYNE K	
			ART UNIT 1743	PAPER NUMBER

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,154

Applicant(s)

CHANDLER, HOWARD MILNE

Examiner

Dwayne K Handy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 2, 4-6, 8, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kagaya (EP 0727653) in view of Grow et al. (EP 0281251). Kagaya teaches a device and method for sampling feces. The device includes a main container (13) which holds a sample collecting stick (15) with a brush portion (18) on the end. The brush is submerged in a liquid (12) that is contained in the lower portion of the main container (13). The device is best shown in Figure 1 and described in column 3, line 35 – column 4, line 8. Collection of a feces sample using the collecting stick is also described in this passage at col. 3, line 48: “feces can be collected by rolling the brush

over the feces". This step is also repeated in column 4 in describing use of the brush element as shown in Figures 3 and 4. Kagaya, then, teaches the collection of a fecal sample and the placing of that sample into a collection container where it is mixed with a liquid. Kagaya does not teach the testing of a fluid sample derived from fecal material. Kagaya merely teaches the collection and storage of the sample. Kagaya also does not teach an assay kit for the testing of fecal material since Kagaya does not include means for detecting an analyte in a sample derived from the fecal material.

Grow et al. teach methods for testing samples derived from fecal material. The samples are exposed to assaying materials comprised of adding fecal samples to a container and then adding assaying chemicals – including chemicals for immunoassays to identify analytes in the fecal material. Grow also teaches the testing of multiple samples by diluting the original sample through transferring portions of the original sample to multiple containers (page 5, lines 54-56). Grow does not teach the collection of sample material with the use of a brush or brush-like device. Grow merely recites the placement of sample material in a container where the assay takes place. It would have been obvious to one of ordinary skill in the art to combine the assay steps of Grow with the collection steps of Kagaya. Kagaya teaches the collection of a fecal sample with a brush that is then held in a liquid that suspends parts of the sample and keep it until the contents of the brush and container are assayed. The use of Cayuga's device would allow for the storage of the fecal sample until they could be later tested. The use of the brush to transfer sample material from the collection container would allow for the

transfer of both solid and liquid materials trapped in the brush from Kagaya to different containers where multiple assays could be conducted on the fecal samples.

4. Claims 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kagaya (EP 0727653) in view of Grow et al. (EP 0281251) and further in view of Hori et al. (5,460,781). Kagaya and Grow, as combined in paragraph 3 above, teach every element of claims 3 and 10 except for the specific bristle length. Hori et al. teaches a hemoglobin sampler for use with stool samples for clinical tests. The device securely samples occult hemoglobin with water content. The sample is comprised of a core member having a porous fiber bundle made up of fibers of 5-7 mm in length (column 4, lines 23-31). As noted by the reference, this is one of the dimensions which are extremely convenient for sampling and capturing occult hemoglobin. It would be obvious to one of ordinary skill in the art to combine the fiber dimensions from the sampler of Hori with the combined brush teachings of Kagaya and Grow. One would use this dimension for capturing occult hemoglobin as taught by Hori.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kagaya (EP 0727653) in view of Grow et al. (EP 0281251) and further in view of Schreiber (5,264,181). Schreiber teaches the detection of occult blood in fecal matter using a guaiac test. The fecal sample is placed on the window opening of a test device containing the guaiac reagents and allowed to react. A color change in the testing device reveals whether or not blood is present in the fecal matter. It would have been

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obvious to one of ordinary skill in the art to perform the guaiac test from Schreiber to determine the presence of blood in a fecal sample. One would perform the guaiac test as an additional check for blood material in the fecal sample in combination with the assay materials used in Grow.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fisher (6,171,259 and 5,265,620) shows a combined fecal specimen sampler and temperature measuring device. Diamond et al. (6,063,038) show a fecal sampling brush. Karakawa (5,543,115) and Tobin et al. (3,792,699) teach sample handling containers. Turkel et al. (5,792,074) and Levene (3,881,464) teach medical probe devices with brush elements. Schwartz (4,539,180), Fleisher et al. (4,492,124), and Brush et al. (3,783,998) show devices for acquiring fecal samples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9310.

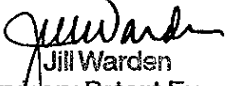
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.

Dkh
December 8, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700